

INDUSTRY CIRCULAR

OFFICE OF THE COMMISSIONER OF INTERNAL REVENUE
ALCOHOL AND TOBACCO TAX DIVISION



WASHINGTON 25, D. C.

Industry Circular No. 65-4

February 18, 1965

WITHDRAWAL OF PERMISSION TO USE COLOR ADDITIVE - FD&C RED NO. 4

Proprietors of distilled spirits plants,
breweries, manufacturers of nonbeverage
products, and others concerned:

This is to advise you that after June 9, 1965, the Food and Drug Administration will consider as adulterated any food or ingested drugs and cosmetics which contain the color additive, FD&C Red No. 4. Test animals fed with substances containing this ingredient developed urinary bladder and adrenal disorders.

In view thereof, pending requests and formulas on Forms 27-B Supplemental or 1678 calling for the use of this color agent will not be approved by the Director, Alcohol and Tobacco Tax Division. Proprietors should examine any previously approved requests or formulas to determine whether the additive is among the manufacturing ingredients. New formulas on Form 1678 or amended formulas or riders on Form 27-B Supplemental may be filed to delete FD&C Red No. 4 or to substitute an approved coloring agent. It will be very helpful if any other previously approved requests are returned promptly to your Assistant Regional Commissioner for cancellation.

The Food and Drug Administration is engaged in a continuing effort to establish safety levels for the use of food additives. Proprietors who submit requests or formulas for approval should be aware of the listing of currently approved ingredients and be guided accordingly. Approval of requests and formulas under internal revenue law and regulations does not authorize the use of materials or ingredients prohibited by other Federal laws or regulations.

Inquiries regarding this circular should refer to its number and be addressed to your Assistant Regional Commissioner, Alcohol and Tobacco Tax.

A handwritten signature in cursive script, reading "Harold A. Serr".

Harold A. Serr
Director, Alcohol and Tobacco Tax Division